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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/492,763	01/27/2000	Eiko Masatsuji	Q54487	1343

7590

05/16/2003

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EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 05/16/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/492,763

Applicant(s)

MASATSUJI ET AL.

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Continued Prosecution Application

1. The request filed on October 09, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/492,763 is acceptable and a CPA has been established. An action on the CPA follows.

Status of Application

2. Acknowledgement is made of amendment filed on 10/09/2002. Claim 9 is requested to be canceled. The claims 1-6 and 16-20 are pending. Since Parent application(09/492,763) was subject to a restriction practice and the group I, the elected claims 1-6(claim 9 is canceled) are presented for the examination and the non-elected claims 16-20 are withdrawn from the consideration in this continued prosecution application(CPA).

Response to Arguments

Applicant's arguments filed October 9, 2002 have been fully considered but they are not persuasive. As admitted by applicants in their remarks(filed 10/9/2002) at page 3, Sano'919 teaches a zinc salt of ascorbic acid -2-phosphate(APZ). Applicants argued that Sano'919 fails to teach acne treatment. It is noted that the instant claims 1-6 are directed a composition comprising a therapeutically effective amount of APZ. rather than the use(e.g. acne treatment, reduction of skin irritation, etc). It is clearly stated in the court decision, applicant is not entitled to procure claims based on discovery that known composition of matter can be adapted to new use; to entitle him to patent, composition

Art Unit: 1614

must both new and unobvious to one skilled in art. *In re Hack*, 114 USPQ 161. Thus, the claims are maintained in the same rejection as follows.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sano et al(US 5,516,919) in view of Fahim(US 4,372,296).

The claims are drawn to a dermal agent comprising agent comprising a therapeutically effective amount (0.01-90%) of a zinc salt of ascorbic acid derivative represented by the formula (3).

Sano et al(US'919) teach a stable topical composition comprising a effective amount of metal salts of ascorbic acid-2-phosphate used in the field of cosmetics and medicines, see column 1, lines 5-10. US '919 also teaches its beneficial use in the cosmetic and pharmaceutical field where the salt of ascorbic -2-phosphate shown the superior quality than conventional ascorbic acid preparations. It further teaches salt formation process using zinc carbonate as a source for metal salt, see column 2, line 31-32. Although Sano fails to exemplified specific example containing a zinc salt of ascorbic acid-2-phosphate, one would have been readily envisaged a zinc salt of

Art Unit: 1614

ascorbic acid -2-phosphate as a final product resulted from said salt formation process when it is viewed by other examples. For instance, ammonium or magnesium salt of ascorbic acid-2-phosphate is produced by same salt formation process using ammonium solution or alkali metal(e.g. magnesium), see column 2, lines 29-34. The salt formation techniques are conventionally knowledge and also evidenced by Sano's patente, and thus, the claimed subject matter is not patentably distinct over the prior art of the record.

Alternatively, even if said envision is not readily occurred, it would have been obvious to one of ordinary skill in the art to formulate the zinc salt of ascorbic acid-2-phosphate when Sano et al is taken in view of Fahim because Fahim teaches a topical composition containing a synergistic combination of zinc salt and ascorbic acid in acne treatment via stimulating collagen production and by killing the normal microflora(e.g. staphylococcus) found in the pilosebaceous ducts, see column 3, lines 7-37 and example 1.

Thus, one would have been motivated to use zinc carbonate to make a zinc salt of ascorbic acid -2-phosphate because that a zinc salt of ascorbic acid-2-phosphate have the synergistic combination of zinc ion and ascorbic acid and it maximizes the therapeutic efficacy while it reduces the skin irritation. Because of the synergistic combination requires small dose of each active agent, one could minimize the skin irritation that is caused by excessive amount of zinc or ascorbic acid. Nevertheless, achieving less skin irritations, inhibitory effect(staphylococcus, etc) recited in the preambles(claims 1-6) is inherent feature where it is naturally occurring when the

Art Unit: 1614

therapeutically effective amount of a zinc salt of ascorbic acid -2-phosphate is applied topically. It is noted that a recitation of the intended use of the claimed invention, in case of the claimed invention is directed to the composition claims, must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

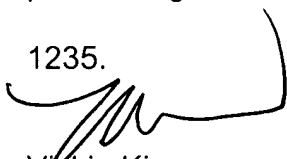
Thus the claimed subject matter is not patentably distinct over the prior art.

Conclusion

1. No claim is allowed.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM) .

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-

1235.



Vickie Kim,
Patent examiner
Art unit 1614

May 15, 2003